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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,603	10/09/2001	Matthew G. Fishler	98P1008US02	4373
36802	7590	10/21/2004	EXAMINER	
PACESETTER, INC. 15900 VALLEY VIEW COURT SYLMAR, CA 91392-9221			SCHAETZLE, KENNEDY	
			ART UNIT	PAPER NUMBER
			3762	
DATE MAILED: 10/21/2004				

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/976,603	Applicant(s) FISHLER ET AL.	
	Examiner Kennedy Schaetzle	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 03 August 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-16 and 18-21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,6,9 and 11 is/are rejected.
- 7) ☒ Claim(s) 3-5,7,8,10,12-16 and 18-21 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on August 3, 2004 has been entered.

Claim Objections

2. Claims 6 and 20 are objected to because of the following informalities: in both claims, either typographical or scanning errors have occurred eliminating the "e" from the word "the" (claim 6, line 2) and the word "second" (claim 20, line 1). Appropriate correction is required.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1, 6, 9 and 11 are rejected under 35 U.S.C. 102(e) as being anticipated by Lopin et al. (Pat. No. 5,733,310).

Lopin et al. disclose a defibrillator comprising a set of capacitors 20 (note col. 5, lines 1-7) and switching circuitry (H-bridge 48) connected to the capacitors and operative to selectively discharge the capacitors so as to generate a first phase of a

biphasic defibrillation pulse waveform wherein the first phase of the waveform has at least three distinct voltage peaks (see Figs. 1 and 6).

While the examiner is aware that the Lopin et al. invention pertains to external defibrillators, use of the word "implantable" in the preamble of claim 1 fails to saliently distinguish the invention over the prior art since the preamble does not recite essential structure and does not give "...life, meaning, and vitality," to the claim (see *Pitney Bowes*, 51 USPQ 2d 1165-66; *Kropa v. Robie*, 88 USPQ 478, 480, 481 (CCPA 1951)).

Regarding claim 6, the examiner considers this claim to represent a product-by-process claim wherein the applicants are attempting to define the apparatus by the method in which it is made. Since the biphasic waveform produced by the Lopin et al. device is of a similar nature to that produced by the present invention, the reason for selecting capacitance values is immaterial if the end result is substantially equivalent. Applicants' claim 6 simply requires the capacitance to be selected for maximum efficiency of the defibrillator—a long-standing goal in the art. Lopin et al. state that the capacitor stores the minimum amount of energy required to meet the delivered charge requirements (see col. 6, lines 54-59). Simply put, Lopin et al. select the capacitance so that defibrillation can occur using the minimum amount of energy necessary. Furthermore, the recitation "...maximizing a final myocardial voltage..." is a matter of relative comparison. One can say that the capacitance of the Lopin et al. device is selected to maximize a final myocardial voltage as compared to the final myocardial voltage of a prior art defibrillator not employing the improvements disclosed by Lopin et al..

Regarding claim 9, the examiner considers the switching circuitry of Lopin et al. to selectively discharge the capacitors during the at least three steps of the pulse waveform for respective first, second and third time periods. The claim as written does not require any specific discharge arrangement such as set forth in claim 3. A capacitor bank that is discharged while providing the multiple peaked waveform is considered to represent the selective discharge of capacitors during three steps, with the time periods being arbitrarily assigned. The examiner can, for example, consider the first phase of the waveform shown in Fig. 1 to span any number of time periods, including three.

Parallel comments to those made in the rejection of claim 1 apply to method claim 11 as well.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claim 2 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lopin et al. (Pat. No. 5,733,310).

Regarding claim 2, while Lopin et al. do not explicitly refer to the use of first, second and third capacitors, it is taught that a single capacitor or a set of capacitors may be employed in the construction of the invention (col. 5, lines 1-7). Clearly the reference to a set of capacitors includes the use of three capacitors, with the exact number of capacitors being a designer's prerogative dependent upon the required charging and discharging voltages, capacitor construction, overall circuit design, and a host of patient defined parameters. To utilize three capacitors in the device of Lopin et al. would have therefore been considered obvious by those of ordinary skill in the art.

Allowable Subject Matter

7. Claims 3-5, 7, 8, 10, 12-16 and 18-21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Reasons for allowance of claims 3-5, 12-16 and 18-21 can be found in the Office Action mailed May 21, 2004.

Concerning claims 7, 8 and 10, the specific capacitance and time relationships are not disclosed in the prior art of record.

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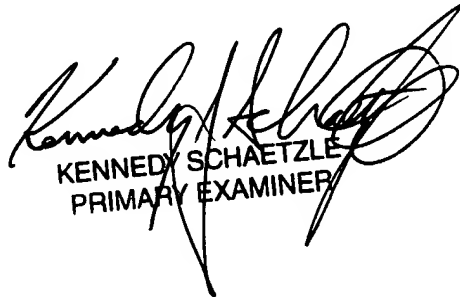
Conclusion

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on M-W, F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

KJS
October 19, 2004


KENNEDY SCHAETZLE
PRIMARY EXAMINER